IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TEVA PHARMACEUTICALS INTERNATIONAL GMBH, CEPHALON, INC., and EAGLE PHARMACEUTICALS, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. 21-695-CFC
DR. REDDY'S LABORATORIES, LTD., and DR. REDDY'S LABORATORIES, INC.,	)	
Defendants.	)	

AMENDED COMPLAINT

Plaintiffs Teva Pharmaceuticals International GmbH ("Teva Pharmaceuticals"), Cephalon, Inc. ("Cephalon") (collectively, with Teva Pharmaceuticals, "Teva"), and Eagle Pharmaceuticals, Inc. ("Eagle") (collectively, "Plaintiffs"), by their attorneys, for their Complaint, allege as follows:

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C., and for a declaratory judgment of patent infringement under 28 U.S.C. §§ 2201 and 2202 and the patent laws of the United States, 35 U.S.C., which arises out of Dr. Reddy's Laboratories Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, "Dr. Reddy's") submission of New Drug Application ("NDA") No. 215668 to the U.S. Food and Drug Administration ("FDA") seeking approval to commercially manufacture, use, offer for sale, sell, and/or import a generic version of Bendeka® (bendamustine hydrochloride) Injection, 100 mg/4 mL (25 mg/mL), prior to

the expiration of, among others, U.S. Patent Nos. 9,572,887 (the "'887 patent") and 11,103,483 (the "'483 patent") (collectively, the "Patents-in-Suit").[1]

PARTIES

2. Plaintiff Teva Pharmaceuticals is a limited liability company organized and existing under the laws of Switzerland, having its corporate offices and principal place of business at Schlüsselstrasse 12, Jona (SG) 8645, Switzerland.

3. Plaintiff Cephalon is a corporation organized and existing under the laws of Delaware, having its corporate offices and principal place of business at 145 Brandywine Parkway, West Chester, Pennsylvania 19380.

4. Plaintiff Eagle is a corporation organized and existing under the laws of Delaware, having its corporate offices and principal place of business at 50 Tice Boulevard, Suite 315, Woodcliff Lake, New Jersey 07677.

5. On information and belief, Defendant Dr. Reddy's Laboratories, Ltd. is a company organized and existing under the laws of the Republic of India having its corporate offices and principal place of business at Door No. 8-2-337, Road No. 3, Banjara Hills, Hyderabad 500 034, Telangana, Republic of India. On information and belief, Dr. Reddy's Laboratories, Ltd. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs through various operating subsidiaries, including Dr. Reddy's Laboratories, Inc.

6. On information and belief, Defendant Dr. Reddy's Laboratories, Inc. is a company organized and existing under the laws of the State of New Jersey having its corporate

[1] Originally, Plaintiffs asserted the '887 patent and U.S. Patent Nos. 8,609,707, 9,265,831, 9,572,796, 9,572,797, 9,034,908, 9,144,568, 9,597,397, 9,597,398, 9,597,399, 9,000,021, 9,579,384, 10,010,533, and 10,052,385. *See* D.I. 1; D.I. 41.

offices and principal place of business at 107 College Road East, Princeton, New Jersey 08540. On information and belief, Dr. Reddy's Laboratories, Inc. is in the business of, among other things, manufacturing and selling generic versions of pharmaceutical drug products throughout the United States, including Delaware.

7. On information and belief, Dr. Reddy's Laboratories, Inc. is a wholly owned subsidiary of Dr. Reddy's Laboratories, Ltd. and the U.S. agent for Dr. Reddy's Laboratories, Ltd.

8. On information and belief, Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. acted in concert to prepare and submit Dr. Reddy's NDA to FDA.

9. On information and belief, Dr. Reddy's Laboratories, Ltd. actively encouraged, recommended, and promoted that Dr. Reddy's Laboratories, Inc. prepare and submit Dr. Reddy's NDA to FDA and knew that the filing of Dr. Reddy's NDA would infringe the Patents-in-Suit, including because Dr. Reddy's Laboratories, Ltd. knew that Dr. Reddy's NDA would include a Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to one or more of the Patents-in-Suit.

10. On information and belief, Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. know and intend that upon approval of Dr. Reddy's NDA, Dr. Reddy's Laboratories, Ltd. will manufacture Dr. Reddy's NDA Product; and Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. will directly or indirectly market, sell, and distribute Dr. Reddy's NDA Product throughout the United States, including in Delaware. On information and belief, Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. are agents of each other and/or operate in concert as integrated parts of the same business group, including with respect to Dr. Reddy's NDA Product, and enter into agreements that are nearer than arm's length. On

information and belief, Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. participated, assisted, and cooperated in carrying out the acts complained about herein.

11. On information and belief, following any FDA approval of Dr. Reddy's NDA, Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. will act in concert to distribute and sell Dr. Reddy's NDA Product throughout the United States, including within Delaware.

JURISDICTION AND VENUE

12. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

13. Based on the facts and causes alleged herein, and for additional reasons to be further developed through discovery if necessary, this Court has personal jurisdiction over Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc.

14. This Court has personal jurisdiction over Dr. Reddy's Laboratories, Ltd. because, among other things, Dr. Reddy's Laboratories, Ltd., itself and through its subsidiary Dr. Reddy's Laboratories, Inc., has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. On information and belief, Dr. Reddy's Laboratories, Ltd., itself and through its subsidiary Dr. Reddy's Laboratories, Inc., develops, manufactures, imports, markets, offers to sell, sells, and/or imports generic drugs throughout the United States, including in Delaware, and therefore transacts business within Delaware, and/or has engaged in systematic and continuous business contacts within Delaware.

15. In addition, this Court has personal jurisdiction over Dr. Reddy's Laboratories, Ltd. because, on information and belief, Dr. Reddy's Laboratories, Ltd. directs and

controls Dr. Reddy's Laboratories, Inc., and Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. are alter egos of each other. Therefore, Dr. Reddy's Laboratories, Inc.'s activities in Delaware are attributable to Dr. Reddy's Laboratories, Ltd.

16. This Court has personal jurisdiction over Dr. Reddy's Laboratories, Inc. because, among other things, it has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. On information and belief, Dr. Reddy's Laboratories, Inc. is registered as a pharmacy wholesaler under license No. A-4-0002524 and as a controlled substances distributor/manufacturer under license No. DM-0013148 with the Delaware Division of Professional Regulation. In addition, on information and belief, Dr. Reddy's Laboratories, Inc. develops, manufactures, imports, markets, offers to sell, sells, and/or imports generic drugs throughout the United States, including in Delaware, and therefore transacts business within Delaware relating to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within Delaware.

17. In addition, this Court has personal jurisdiction over Dr. Reddy's Laboratories, Inc. because, on information and belief, Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. are alter egos of each other. Therefore, Dr. Reddy's Laboratories, Ltd.'s activities in Delaware are attributable to Dr. Reddy's Laboratories, Inc.

18. In addition, this Court also has personal jurisdiction over Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. because, among other things, on information and belief: (1) Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. filed Dr. Reddy's NDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Dr. Reddy's NDA Product in the United States, including in Delaware; and (2) upon approval of Dr. Reddy's NDA, Dr. Reddy's Laboratories, Ltd. and Dr.

Reddy's Laboratories, Inc. will market, distribute, offer for sale, sell, and/or import Dr. Reddy's NDA Product in the United States, including in Delaware, and will derive substantial revenue from the use or consumption of Dr. Reddy's NDA Product in Delaware. *See Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755, 763 (Fed. Cir. 2016). On information and belief, upon approval of Dr. Reddy's NDA, Dr. Reddy's NDA Product will, among other things, be marketed, distributed, offered for sale, sold, and/or imported in Delaware; prescribed by physicians practicing in Delaware; dispensed by pharmacies located within Delaware; and/or used by patients in Delaware, all of which would have a substantial effect on Delaware.

19. In addition, this Court has personal jurisdiction over Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. because they have committed, aided, abetted, induced, contributed to, or participated in the commission of the tortious act of patent infringement that has led and/or will lead to foreseeable harm and injury to Cephalon and Eagle, both Delaware corporations.

20. In addition, this Court has personal jurisdiction over Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. because they regularly engage in patent litigation concerning Dr. Reddy's NDA or Abbreviated New Drug Application ("ANDA") Products in this District, do not contest personal jurisdiction in this District, and have purposefully availed themselves of the rights and benefits of this Court by asserting claims and/or counterclaims in this District, including in this litigation. D.I. 16.[2]

[2] *See also, e.g.*, *Bial Portella & CA S.A. et al. v. Dr. Reddy's Labs., Ltd. & Dr. Reddy's Labs., Inc.*, C.A. No. 21-188-CFC (D. Del. Mar. 3, 2021), D.I. 6, at 4-6; *Intercept Pharm., Inc. et al. v. Dr. Reddy's Labs., Inc. Dr. Reddy's Labs., Ltd.*, C.A. No. 21-35-MN (D. Del. Feb. 5, 2021), D.I. 10, at 5-9, 39-59; *Pfizer, Inc. et al. v. Dr. Reddy's Labs., Inc. & Dr. Reddy's Labs., Ltd.*, C.A. No. 20-1530-CFC (D. Del. Jan. 15, 2021), D.I. 10, at 3-4; *Novartis Pharm. Corp. v. Dr. Reddy's Labs., Inc.. & Dr. Reddy's Labs., Ltd. et al.*, C.A. No. 19-2053-LPS (D. Del. Feb. 6, 2020), D.I. 34, at 3-8. 29-32, 85-103; *Genzyme Corp. et al. v. Dr. Reddy's Labs., Inc.. & Dr.*

21. For the above reasons, it would not be fundamentally unfair or unreasonable for Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. to litigate this action in this District, and the Court has personal jurisdiction over them here.

VENUE

22. Plaintiffs incorporate each of the proceeding paragraphs 1–21 as if fully set forth herein.

23. Venue is proper in this District under 28 U.S.C. §§ 1391 and 1400(b) with respect to Dr. Reddy's Laboratories, Ltd., at least because, on information and belief, Dr. Reddy's Laboratories, Ltd. is a foreign corporation that may be sued in any judicial district in which it is subject to the Court's personal jurisdiction.

24. Venue is proper in this District under 28 U.S.C. § 1400(b) with respect to Dr. Reddy's Laboratories, Inc., at least because, on information and belief, Dr. Reddy's Laboratories Ltd. is the U.S. agent and alter ego of Dr. Reddy's Laboratories, Ltd. (which is subject to venue in this District). In addition, Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. regularly engage in patent litigation concerning Dr. Reddy's NDA or ANDA Products in this District, do not contest venue in this District, and assert claims and/or counterclaims in this District, including in this litigation. D.I. 16.[3]

BACKGROUND

Reddy's Labs., Ltd., C.A. No. 18-1839-CFC (D. Del. Jan. 16, 2019), D.I. 13, at 2-3, 9-15; *Onyx Therapeutics, Inc. v. Dr. Reddy's Labs., Ltd. & Dr. Reddy's Labs., Inc.*, C.A. No. 17-1811-LPS (D. Del. Jan. 23, 2018), D.I. 11, at 4-7, 43-63; *Bristol Myers Squibb Co. et. al. v. Dr. Reddy's Labs., Ltd. & Dr. Reddy's Labs., Inc.*, C.A. No. 17-401-LPS (D. Del. July 7, 2017), D.I. 11, at 3, 9-14; *Amgen Inc. v. Dr. Reddy's Labs., Ltd. & Dr. Reddy's Labs., Inc.*, C.A. No. 16-900-GMS (D. Del. Nov. 1, 2016), D.I. 8, at 1-2, 7-11.

[3] *See also supra* n.1.

25. Bendeka®, which contains bendamustine hydrochloride, is an alkylating drug that is indicated for the treatment of patients with (1) chronic lymphocytic leukemia and (2) indolent B-cell non-Hodgkin lymphoma that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen.

26. Eagle is the holder of NDA No. 208194 for Bendeka®, which has been approved by FDA.

27. The ’887 patent, entitled “Formulations of Bendamustine” (Exhibit A), was duly and legally issued on February 21, 2017. Eagle Pharmaceuticals, Inc. is the owner and assignee of the ’887 patent, subject to the exclusive license referenced herein. The ’887 patent has been listed in connection with Bendeka® in the Orange Book.

28. The ’483 patent, entitled “Formulations of Bendamustine” (Exhibit B), was duly and legally issued on August 31, 2021. Eagle Pharmaceuticals, Inc. is the owner and assignee of the ’483 patent, subject to the exclusive license referenced herein. The ’483 patent has been listed in connection with Bendeka® in the Orange Book.

29. On or around February 13, 2015, Cephalon executed an exclusive license (the “Eagle License”) to, among other things, U.S. Patent No. 8, 609,707; U.S. Patent Application Nos. 14/031,879, 13/838,090, and 13/838,267; and all patent rights claiming priority to those patents or patent applications (which include, among others, the ’887 and ’483 patents), for the commercialization of Eagle’s bendamustine hydrochloride rapid infusion product, EP-3102, which became Bendeka®. The Eagle License provides Cephalon the right to sue for infringement of the licensed patents in the event of, among other things, the filing of an NDA that makes reference to Bendeka® and seeks approval before expiry of a licensed patent.

30. On or around October 14, 2015, Cephalon assigned its rights in the Eagle License to Teva Pharmaceuticals.

INFRINGEMENT BY DR. REDDY'S

31. By letter dated March 31, 2021 ("Dr. Reddy's Notice Letter"), Dr. Reddy's Laboratories, Inc., as U.S. agent for Dr. Reddy's Laboratories Ltd., notified Teva and Eagle that it had filed a Paragraph IV Certification with respect to the '887 patent, among others, and was seeking approval from FDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Dr. Reddy's NDA Product prior to the expiration of the '887 patent. On information and belief, Dr. Reddy's NDA contains a Paragraph IV Certification asserting that the '887 patent will not be infringed by the manufacture, use, offer for sale, sale, or importation of Dr. Reddy's NDA Product, or alternatively, that the '887 patent is invalid.

32. The purpose of Dr. Reddy's submission of Dr. Reddy's NDA was to obtain approval under the Federal Food, Drug and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Dr. Reddy's NDA Product prior to the expiration of the Patents-in-Suit.

33. In Dr. Reddy's Notice Letter, Dr. Reddy's stated that the active ingredient of Dr. Reddy's NDA Product is bendamustine hydrochloride.

34. In Dr. Reddy's Notice Letter, Dr. Reddy's stated that Dr. Reddy's NDA Product contains 100 mg/4 mg (25 mg/mL) bendamustine hydrochloride.

35. In Dr. Reddy's Notice Letter, Dr. Reddy's did not disclose the composition of Dr. Reddy's NDA product and furnish samples, data, or other information sufficient to confirm independently the exact composition of Dr. Reddy's NDA product and assess the properties and functions of Dr. Reddy's NDA Product.

36. In Dr. Reddy's Notice Letter, Dr. Reddy's did not contest infringement, among other things, of claims 1-3, 8-13, or 16-29 of the '887 Patent. For example, claim 1 of the '887 Patent recites: "1. A method of treating chronic lymphocytic leukemia or indolent B cell non-Hodgkin's lymphoma in a subject comprising: a. providing a non-aqueous liquid composition comprising from about 10 mg/mL to about 100 mg/mL of bendamustine or a pharmaceutically acceptable salt thereof, wherein the total impurities are less than about 5% as determined by HPLC at a wavelength of 223 nm after 15 months at a temperature of from about 5° C. to about 25° C.; b. diluting said non-aqueous liquid composition with a parenterally acceptable aqueous diluent; and c. parenterally administering said diluted composition to the subject at a bendamustine dosage ranging from about 25 mg/m^2 to about 120 mg/m^2, wherein said administering step is performed with a total volume of about 100 mL or less of the diluted composition administered over a period of less than or equal to about 15 minutes." Claim 2 of the '887 Patent recites: "2. The method of claim 1, wherein the non-aqueous liquid composition comprises a pharmaceutically acceptable fluid comprising polyethylene glycol, propylene glycol, ethanol, benzyl alcohol, glycofurol, or DMSO, or a mixture thereof." Claim 3 of the '887 Patent recites: "3. The method of claim 1, wherein the non-aqueous liquid composition comprises polyethylene glycol, propylene glycol, or a mixture thereof."

37. On information and belief, Dr. Reddy's NDA Product contains bendamustine, polyethylene glycol, and a stabilizing amount of an antioxidant, or equivalent ingredients, in the same or equivalent amounts as Bendeka®.

38. On information and belief, Dr. Reddy's NDA Product is a ready to use liquid bendamustine-containing composition.

39. On information and belief, Dr. Reddy's NDA Product has less than about 5% peak area response of total impurities resulting from the degradation of the bendamustine, as determined by HPLC at a wavelength of 223 nm after at least 15 months at a temperature of from about 5 °C to about 25 °C.

40. On information and belief, the proposed labeling for Dr. Reddy's NDA Product recommends, encourages, instructs, and/or promotes administration to patients with chronic lymphocytic leukemia, which is a type of cancer.

41. On information and belief, the proposed labeling for Dr. Reddy's NDA Product recommends, encourages, instructs, and/or promotes administration of a bendamustine dose of 100 mg/m^2 to patients with chronic lymphocytic leukemia.

42. On information and belief, the proposed labeling for Dr. Reddy's NDA Product recommends, encourages, instructs, and/or promotes administration to patients with indolent B-cell non-Hodgkin lymphoma, which is a type of cancer.

43. On information and belief, the proposed labeling for Dr. Reddy's NDA Product recommends, encourages, instructs, and/or promotes administration of a bendamustine dose of 120 mg/m^2 to patients with indolent B-cell non-Hodgkin lymphoma.

44. On information and belief, the proposed labeling for Dr. Reddy's NDA Product recommends, encourages, instructs, and/or promotes the administration of Dr. Reddy's NDA Product in a volume of about 50 mL or less over a time period of about 10-minutes or less.

45. In an exchange of correspondence, counsel for Teva and counsel for Dr. Reddy's discussed the terms of Dr. Reddy's Offer for Confidential Access. The parties did not agree on terms under which Teva could review, among other things, Dr. Reddy's NDA and certain portions of the Drug Master File referred to therein, and Dr. Reddy's refused to produce samples

of Dr. Reddy's NDA product and other internal documents and materials relevant to infringement. In addition, Dr. Reddy's Offer for Confidential Access placed unreasonable restrictions on the extent to which Teva could access the documents and materials subject to the offer. Without all of the materials requested by Teva, including samples of Dr. Reddy's NDA product, which Dr. Reddy's refused to produce, Teva could not confirm, and cannot confirm, the exact composition and properties of Dr. Reddy's NDA product. Dr. Reddy's filing of its NDA seeking approval to market a generic version of Bendeka® before expiry of the patents asserted herein constitutes an act of infringement.

46. On May 12, 2021, shortly before forty-five days had elapsed following Plaintiffs' receipt of Dr. Reddy's Notice Letter, counsel for Dr. Reddy's responded to Teva's most-recent correspondence regarding Dr. Reddy's Offer for Confidential Access, and the parties recognized that they were at an impasse.

47. This action commenced before the expiration of forty-five days from the date of the receipt of Dr. Reddy's Notice Letter.

COUNT I – INFRINGEMENT BY DR. REDDY'S OF U.S. PATENT NO. 9,572,887 UNDER 35 U.S.C. § 271(e)(2)

48. Plaintiffs incorporate each of the preceding paragraphs 1–46 as if fully set forth herein.

49. Dr. Reddy's submission of Dr. Reddy's NDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Dr. Reddy's NDA Product prior to the expiration of the '887 patent was an act of infringement of the '887 patent under 35 U.S.C. § 271(e)(2)(A).

50. In its Notice Letter, Dr. Reddy's did not contest that at least some claims of the '887 patent, including claim 1, cover the use of Dr. Reddy's NDA Product as directed by Dr. Reddy's proposed labeling.

51. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Dr. Reddy's NDA Product would infringe one or more claims of the '887 patent, either literally or under the doctrine of equivalents.

52. On information and belief, Dr. Reddy's will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Dr. Reddy's NDA Product immediately and imminently upon FDA approval of Dr. Reddy's NDA.

53. On information and belief, the use of Dr. Reddy's NDA Product in accordance with and as directed by Dr. Reddy's proposed labeling for that product would infringe one or more claims of the '887 patent.

54. On information and belief, Dr. Reddy's plans and intends to, and will, actively induce infringement of the '887 patent when Dr. Reddy's NDA is approved, and plans and intends to, and will, do so after approval.

55. On information and belief, Dr. Reddy's knows that Dr. Reddy's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '887 patent and that Dr. Reddy's NDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Dr. Reddy's plans and intends to, and will, contribute to infringement of the '887 patent after approval of Dr. Reddy's NDA.

56. The foregoing actions by Dr. Reddy's constitute and/or will constitute infringement of the '887 patent, active inducement of infringement of the '887 patent, and contribution to the infringement by others of the '887 patent.

57. On information and belief, Dr. Reddy's has acted with full knowledge of the '887 patent and without a reasonable basis for believing that it would not be liable for infringing the '887 patent, actively inducing infringement of the '887 patent, and contributing to the infringement by others of the '887 patent.

58. Unless Dr. Reddy's is enjoined from infringing the '887 patent, actively inducing infringement of the '887 patent, and contributing to the infringement by others of the '887 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT II – INFRINGEMENT BY DR. REDDY'S OF U.S. PATENT NO. 11,103,483 UNDER 35 U.S.C. § 271(e)(2)

59. Plaintiffs incorporate each of the preceding paragraphs 1–58 as if fully set forth herein.

60. Dr. Reddy's submission of Dr. Reddy's NDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Dr. Reddy's NDA Product prior to the expiration of the '483 patent was an act of infringement of the '483 patent under 35 U.S.C. § 271(e)(2)(A).

61. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Dr. Reddy's NDA Product would infringe one or more claims of the '483 patent, either literally or under the doctrine of equivalents.

62. On information and belief, Dr. Reddy's will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Dr. Reddy's NDA Product immediately and imminently upon FDA approval of Dr. Reddy's NDA.

63. On information and belief, the use of Dr. Reddy's NDA Product in accordance with and as directed by Dr. Reddy's proposed labeling for that product would infringe one or more claims of the '483 patent.

64. On information and belief, Dr. Reddy's plans and intends to, and will, actively induce infringement of the '483 patent when Dr. Reddy's NDA is approved, and plans and intends to, and will, do so after approval.

65. On information and belief, Dr. Reddy's knows that Dr. Reddy's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '483 patent and that Dr. Reddy's NDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Dr. Reddy's plans and intends to, and will, contribute to infringement of the '483 patent after approval of Dr. Reddy's NDA.

66. The foregoing actions by Dr. Reddy's constitute and/or will constitute infringement of the '483 patent, active inducement of infringement of the '483 patent, and contribution to the infringement by others of the '483 patent.

67. On information and belief, Dr. Reddy's has acted with full knowledge of the '483 patent and without a reasonable basis for believing that it would not be liable for infringing the '483 patent, actively inducing infringement of the '483 patent, and contributing to the infringement by others of the '483 patent.

68. Unless Dr. Reddy's is enjoined from infringing the '483 patent, actively inducing infringement of the '483 patent, and contributing to the infringement by others of the '483 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT III – DECLARATORY JUDGMENT OF INFRINGEMENT BY DR. REDDY'S OF U.S. PATENT NO. 9,572,887

69. Plaintiffs incorporate each of the preceding paragraphs 1–68 as if fully set forth herein.

70. Dr. Reddy's has knowledge of the '887 patent.

71. In its Notice Letter, Dr. Reddy's did not contest that at least some claims of the '887 patent, including claim 1, cover the use of Dr. Reddy's NDA Product as directed by Dr. Reddy's proposed labeling.

72. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Dr. Reddy's NDA Product would infringe one or more claims of the '887 patent, either literally or under the doctrine of equivalents.

73. On information and belief, Dr. Reddy's will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Dr. Reddy's NDA Product with its proposed labeling upon FDA approval of Dr. Reddy's NDA.

74. On information and belief, the use of Dr. Reddy's NDA Product in accordance with and as directed by Dr. Reddy's proposed labeling for that product would infringe one or more claims of the '887 patent.

75. On information and belief, Dr. Reddy's plans and intends to, and will, actively induce infringement of the '887 patent when Dr. Reddy's NDA is approved, and plans and intends to, and will, do so after approval.

76. On information and belief, Dr. Reddy's knows that Dr. Reddy's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '887 patent and that Dr. Reddy's NDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Dr. Reddy's plans and intends to, and will, contribute to infringement of the '887 patent after approval of Dr. Reddy's NDA.

77. The foregoing actions by Dr. Reddy's constitute and/or will constitute infringement of the '887 patent, active inducement of infringement of the '887 patent, and contribution to the infringement by others of the '887 patent.

78. On information and belief, Dr. Reddy's has acted without a reasonable basis for believing that it would not be liable for infringing the '887 patent, actively inducing infringement of the '887 patent, and contributing to the infringement by others of the '887 patent.

79. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Dr. Reddy's regarding whether Dr. Reddy's manufacture, use, sale, offer for sale, or importation into the United States of Dr. Reddy's NDA Product with its proposed labeling according to Dr. Reddy's NDA will infringe one or more claims of the '887 patent and whether one or more claims of the '887 patent are valid.

80. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Dr. Reddy's NDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '887 patent and that the claims of the '887 patent are valid.

81. Dr. Reddy's should be enjoined from infringing the '887 patent, actively inducing infringement of the '887 patent, and contributing to the infringement by others of the '887 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT IV – DECLARATORY JUDGMENT OF INFRINGEMENT BY DR. REDDY'S OF U.S. PATENT NO. 11,103,483

82. Plaintiffs incorporate each of the preceding paragraphs 1–81 as if fully set forth herein.

83. Dr. Reddy's has knowledge of the '483 patent.

84. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Dr. Reddy's NDA Product would infringe one or more claims of the '483 patent, either literally or under the doctrine of equivalents.

85. On information and belief, Dr. Reddy's will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Dr. Reddy's NDA Product with its proposed labeling upon FDA approval of Dr. Reddy's NDA.

86. On information and belief, the use of Dr. Reddy's NDA Product in accordance with and as directed by Dr. Reddy's proposed labeling for that product would infringe one or more claims of the '483 patent.

87. On information and belief, Dr. Reddy's plans and intends to, and will, actively induce infringement of the '483 patent when Dr. Reddy's NDA is approved, and plans and intends to, and will, do so after approval.

88. On information and belief, Dr. Reddy's knows that Dr. Reddy's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '483 patent and that Dr. Reddy's NDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Dr. Reddy's plans and intends to, and will, contribute to infringement of the '483 patent after approval of Dr. Reddy's NDA.

89. The foregoing actions by Dr. Reddy's constitute and/or will constitute infringement of the '483 patent, active inducement of infringement of the '483 patent, and contribution to the infringement by others of the '483 patent.

90. On information and belief, Dr. Reddy's has acted without a reasonable basis for believing that it would not be liable for infringing the '483 patent, actively inducing infringement of the '483 patent, and contributing to the infringement by others of the '483 patent.

91. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Dr. Reddy's regarding whether Dr. Reddy's manufacture, use, sale, offer for sale, or importation into the United States of Dr. Reddy's NDA Product with its proposed

labeling according to Dr. Reddy's NDA will infringe one or more claims of the '483 patent and whether one or more claims of the '483 patent are valid.

92. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Dr. Reddy's NDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '483 patent and that the claims of the '483 patent are valid.

93. Dr. Reddy's should be enjoined from infringing the '483 patent, actively inducing infringement of the '483 patent, and contributing to the infringement by others of the '483 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request the following relief:

(a) A judgment that Dr. Reddy's has infringed, will infringe, and will induce and contribute to infringement of the '887 and '483 patents (the "Patents-in-Suit").

(b) A judgment that the Patents-in-Suit are valid and enforceable;

(c) A judgment pursuant to, among other things, 35 U.S.C. § 271(e)(4)(A) ordering that the effective date of any FDA approval for Dr. Reddy's to make, use, offer for sale, sell, market, distribute, or import Dr. Reddy's NDA Product, or any product or compound the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the Patents-in-Suit, shall not be earlier than the latest of the expiration dates of the Patents-in-Suit, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A preliminary and permanent injunction pursuant to, among other things, 35 U.S.C. §§ 271(e)(4)(B) and 283 enjoining Dr. Reddy's, its officers, agents, servants, employees

and attorneys, and all persons acting in concert with them, from making, using, selling, offering for sale, marketing, distributing, or importing Dr. Reddy's NDA Product, or any product the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the Patents-in-Suit, or the inducement of or the contribution to any of the foregoing, prior to the latest of the expiration dates of the Patents-in-Suit, inclusive of any extension(s) and additional period(s) of exclusivity;

(e) A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing Dr. Reddy's NDA Product, or any product or compound the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the Patents-in-Suit, prior to the expiration date of the Patents-in-Suit, respectively, will infringe, actively induce infringement of, and/or contribute to the infringement by others of the Patents-in-Suit;

(f) An award of Plaintiffs' damages or other monetary relief to compensate Plaintiffs if Dr. Reddy's engages in the manufacture, use, offer for sale, sale, marketing, distribution, or importation of Dr. Reddy's NDA Product, or any product the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the Patents-in-Suit, or the inducement of or the contribution to any of the foregoing, prior to the latest of the expiration dates of the Patents-in-Suit, inclusive of any extension(s) and additional period(s) of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(C);

(g) A declaration that this case is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

(h) An award of Plaintiffs' costs and expenses in this action; and

(i) Such further and other relief as this Court may deem just and proper.

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